

AMENDMENT AND RESPONSE UNDER 37 C.F.R §1.111

Application No. 10/653,027

Title: Tissue Connector Apparatus and Methods

REMARKS

Reconsideration and withdrawal of the claims rejections, in view of the amendments and arguments presented herein, is respectfully requested.

The pending claims are 1 and 3-35. Claims 33 and 34 are amended. Support for the amendments is found throughout the Specification, for example at page 10 lines 12-29. No new matter has been added by way of these amendments.

Claims 12-17, 19-23, 25, 27, 30, and 31 are objected to as being dependent upon a rejected base claim but would be allowable if rewritten in independent form including all limitations of the base and any intervening claims. Claims 24, 26 and 35 are allowed. Applicants note with appreciation the indication of allowed and allowable subject matter.

35 U.S.C. §102 Rejections

The Examiner rejected claims 1, 3-11, 18, 28, 29, and 32 under 35 U.S.C. §102(b) as being anticipated by O'Connor (U.S. Patent No. 5,450,860). In particular the Examiner alleges that O'Connor disclose a surgical fastener adapted to assume a loop configuration, two flexible members/sutures and two piercing members/needles, and a coupling (recessed shank ends). This rejection is respectfully traversed.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. v. Union Oil of California, 814 F.2d 628,631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). M.P.E.P. 2131.

Applicants respectfully submit that O'Connor does not disclose the tissue connector assembly of the present invention. O'Connor discloses a device comprising a ligament to be tunneled through tissue of a heart valve annulus in several "bites" to create, for example, an annuloplasty. (Col. 3 line 58; Col. 7 lines 40-50). The Examiner alleges that the "two narrow sections", 14 and 20, of the ligament 12 of O'Connor are flexible members. However, the Examiner fails to point out where O'Connor discloses a flexible member *coupled to* an end of a fastener. Likewise the disclosure of O'Connor does not so provide. Claim 1 of the present invention discloses in part a flexible member having a first end portion coupled to a first tissue

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piercing member and a second end portion coupled to the first end portion of the fastener. The Applicants are unclear as to how a narrow section of ligament 12 can be *coupled* to itself. Since O'Connor fails to disclose every element of Applicants' claims, the pending claims are novel over O'Connor.

In addition, the claims which depend from Claim 1 include additional allowable subject matter. For example, O'Connor does not disclose a flexible member comprising a suture coupled to a fastener (Claims 4, 5, 7) nor does O'Connor disclose a flexible member comprising metal and coupled to a fastener (Claims 6, 8). The ligament 12 of O'Connor is disclosed as a wide, flexible ligament of expanded PTFE. (Col. 3 lines 37-38). Likewise O'Connor fails to disclose a surgical clip comprising wire and having open and closed configurations (Claims 28, 29, 32).

For at least these reasons, withdrawal of the 35 U.S.C. § 102(e) rejection of claims 1, 3-11, 18, 28, 29, and 32 is respectfully requested.

The Examiner rejected claims 33 and 34 under 35 U.S.C. §102(b) as being anticipated by Adams (U.S. Patent No. 6,001,110). Adams discloses hemostatic clips designed to arrest gastrointestinal bleeding by restricting the blood flow of an injured blood vessel (column 3, lines 35-37). In particular, Adams discloses that the hemostatic clips can be used to treat gastrointestinal bleeding by compressing tissue (bleeding blood vessels) along the gastrointestinal tract in order to bring about hemostasis. However, there is nothing in Adams that discloses a tissue connector assembly comprising a surgical fastener, which is adapted to assume a loop configuration, a first discrete tissue piercing member and a second discrete tissue piercing member as provided in Applicants' claims. Thus, the pending claims are novel over Adams.

Withdrawal of the 35 U.S.C. § 102(b) rejection of claims 33 and 34 as being anticipated by Adams is therefore respectfully requested.

A request for a three (3) month extension of time under 37 C.F.R. 1.136(a) has been made with this Amendment. Please charge to Deposit Account No. 13-2546 the fee of \$1050.00 which is required for the three-month extension of time.

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If the Examiner comes to believe that a telephone conversation may be useful in addressing any remaining open issues in this case, the Examiner is urged to contact the undersigned agent at 763-505-8418.

Please charge any additional required fees or credit any overpayment to Deposit Account No. 13-2546.

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